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510(k) Summary

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<u>Trade Name</u> Clinical Neuro Systems Interchangeable Bit Cranial Drill

Common Name Cranial Drill

<u>Classification Name</u> Manual Cranial Drill, Burr, Trephine, and Accessories

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Predicate Device Identification
PS Medical Ventriculostomy Kit: Cranial Drill
Camino Laboratories Twist Drill Procedure Kit: Cranial Drill
Clinical Neuro Systems Cranial Drill

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Product Description

Clinical Neuro Systems Interchangeable Bit Cranial Drill consists of various bit sizes used during a ventriculostomy procedure. The product includes a hand drill with variable chuck, a 0.156" (3.97mm) drill bit with depth guard, a 0.209" (5.31mm) drill bit with depth guard. The depth guard allows accurate, secure, and easy to use adjustment of cranial drill depth. Cranial drill depth is selected by setting the depth guard to the required distance. The Cranial Drill allows for access to the subarachnoid space or the lateral ventricles of the brain. The Cranial Drill is supplied sterile, double CSR wrapped in a Chevron pouch.

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Intended Use

The drill is intended to be used with an external drainage and monitoring system in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF, and to monitor ICP. The drill is intended for single use only.

VI Technological Comparison To Predicate Devices

Item	CNS Cranial Drill	PS Medical Kit Drill	Camino Kit Drill
1. Hand Drill	Fiskars Twist Drill	Fiskars Twist Drill	Fiskars Twist Drill
2. Drill Bit Included with Drill	Yes	Yes	Yes
3. Integral Bit	Yes	Yes	NA
Adjustable Depth Guard	Yes	Yes	No
5. Set Screw wit Hex Wrench	h No	Yes	Yes
6. Packaging	Sterile, CSR Wrap in Peal Pouch	Sterile, CSR Wrap in Tray and Heade Bag	•

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Test Data

The following tests were performed to ensure acceptable performance of the Clinical Neuro Systems Interchangeable Bit Cranial Drill.

Test	Result
Sterility	Acceptable
Performance	Acceptable
Cytotoxicity	Acceptable
Comparative Evaluation	Acceptable